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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/759,904

01/16/2004

Eric J. Beckman

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1518

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

01/16/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/759,904	Applicant(s) BECKMAN ET AL.	
	Examiner JAMES W. ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-103 is/are pending in the application.
- 4a) Of the above claim(s) 12-14, 17, 27-68 and 70-103 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-11, 15, 16, 18-26 and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/05/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claim 12 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 08/15/2006 to elect an aliphatic multifunctional isocyanate precursor. Since applicants have amended claim 12 to recite an amino acid based isocyanate precursor the claim is now drawn to an unelected species.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,3,7-8,10-11,19-22,27,34-35 and 69 are rejected under 35

U.S.C. 102(b) as being anticipated by Lipatova et al. (Macromol. Symp. 152,139-150 (2000)), for the reasons set forth in the office action filed 11/30/2007.

Claims 1,3-11,15-16,18-20,22,25 and 69 are rejected under 35 U.S.C. 102(e) as being anticipated by Beckman et al. (US 7,264,823 B2), for the reasons set forth in the office action filed 11/30/2007.

Claims 1,3-4,7-8,12,19,22,27-30,33 and 69 are rejected under 35 U.S.C. 102(e) as being anticipated by Woodhouse et al. (US 6,221,997 B1), for the reasons set forth in the office action filed 11/30/2007.

Claims 1,3-11,15-16,18-26 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (Biomaterials 21 (2000) 1247-1258) in view of Liptova et al. (Macromol. Symp. 152, 139-150 (2000)) or in view of Woodhouse et al. (US 6,221,997 B1), for the reasons set forth in the office action filed 11/30/2007.

Response to Arguments

Applicant's arguments filed 11/03/2008 have been fully considered but they are not persuasive.

Applicants assert that none of the references above describe reacting a multifunctional isocyanate with a bioactive agent in water. Applicants assert that water exerts an effect on the reaction in that it acts as a chain extender; therefore the examiner cannot ignore the limitation as this leads to a patentable distinction.

The relevance of this assertion is unclear. Firstly applicant's product shown at the top of page 21 in the second scheme from the top is incorrect, it should be a polyurethane, (note the oxygen between the carbonyl carbon and the nitrogen --RHNCOONHR--). Even if applicants are correct in that water acts as a chain extender for the reaction (something which is not recited within claims 1 or 69) the polyurethane produced is still the same as those described in the references above. Water does not change the chemical structure of the product; it is still a polyurethane that is the same as the polyurethanes described in the references cited above. All that claims 1 and 69 as currently amended require is a polyurethane composition formed from the reaction of an isocyanate and a bioactive agent. Since the references alone or in combination are within the scope of applicants claimed polyurethane composition the rejections stand. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Furthermore applicants note at paragraph [0008] within their own specification that Zhang and coworkers used water as chain extenders for the prepolymers. Also Beckman describes using water in reactions of LDI and glucose to make a foamed material. See col 8 lin 21-55. Furthermore as stated throughout Beckman a mixture of molecules that includes a multi-isocyanate functional groups and a multi functional precursor molecule form a

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crosslinked polymer network upon contact with organic tissue in the presence of **water**.

See previous office actions and abstract of Beckman.

Applicants also assert that it is not clear from Liptova if HDI was combined with Heparin.

The examiner respectfully disagrees. Clearly the use of HDI as a diisocyanate is described within the section of the paper discussing hemocompatible segmented polyurethanes containing heparin fragments.

Conclusion

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618